

MASTER OF SCIENCE IN HEALTH SCIENCES IN LEADERSHIP AND STRATEGY IN REGULATORY AFFAIRS AND CLINICAL RESEARCH ADMINISTRATION

The regulation of clinical research is in itself a dynamic and emergent field. It brings together the science in which products—drugs, devices, biologics and vaccines—and treatment protocols are developed for improved global health care. Both the master’s degree and graduate certificate programs prepare scientists and regulatory professionals to manage the key elements of the clinical research regulatory process. The rigorous curriculum focuses on regulatory strategy, regulatory guidance, legal and ethical issues, processes for product development and the business and political components of regulation in clinical research, all while reinforcing the science behind the methods. Program graduates develop knowledge and skills in regulatory strategy and clinical conduct to guide the development of new therapeutics.

The distance education format provides a contemporary option for self-directed professionals who work in the field with industry or who may be just entering the field with one of the health and human services agencies charged with providing oversight and guidance to industry. Our course work has been developed in partnership with colleagues in industry and public regulatory agencies. The core courses will provide our students with the foundation to support new product development based on the conduct and regulation of clinical trials including registration by health authorities and strategies to manage product updates and post-approval commitments. The curriculum is taught by faculty members who bring both the perspectives of the sponsor and those of public health agencies.

As a result, the program provides each graduate with a robust academic education, while giving the student access to key leaders and practitioners in regulatory affairs and clinical research. This program has been strategically designed to generate leaders who will meet the needs of the emerging trends in regulatory affairs.

Visit the [program website](#) for additional program information.

ADMISSIONS

Admissions Deadlines:	Fall - August 6
	Spring - December 6
	Summer - March 15
	The application and all supporting documentation (fees, statement of purpose, letters of recommendation, transcripts) must be received by the deadline in order for the application to be reviewed.
Standardized Test Scores:	Not required

Recommendations required:	Two (2) recommendations
Prior Academic Records:	Transcripts required from all colleges and universities attended, whether or not credit was earned, the program was completed, or the credit appears as transfer credit on another transcript. Transcripts must be forwarded in their original sealed envelopes.

If academic records are in a language other than English, a certified English language translation must be provided in addition to the original transcripts; translations alone will not be accepted.

Official transcripts from institutions outside the U.S. must be accompanied by an official transcript evaluation from an accredited independent evaluating agency. Please be sure you request a detailed evaluation that includes all course titles, credit hours, grades, U.S. degree equivalency, grade-point averages (GPA), and date of degree conferral. For a list of acceptable foreign credential evaluation services, please follow this link: <https://www.naces.org/members> (<https://www.naces.org/members/>).

Statement of Purpose:	In an essay of 250 to 500 words, describe your reasons for undertaking study in the Health Sciences at The George Washington University. You should state your academic objectives, career plans, and related qualifications, including collegiate, professional, and community activities, as well as any other substantial accomplishments not already mentioned on the application form.
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Degree and GPA Requirements	Bachelor’s degree from a regionally accredited institution 3.0 GPA or above on a 4.0 scale
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International Applicants:

Please follow this link - <https://graduate.admissions.gwu.edu/international-student-application-requirements> (<https://graduate.admissions.gwu.edu/international-student-application-requirements/>) - to review the International Applicant Information carefully for details on required documents and English language requirements.

PLEASE NOTE that the Health Sciences programs require the following minimum English language test scores for admission:

- Academic IETLS: an overall band score of 7.0 with no individual band score below 6.0; or

- TOEFL: 600 on paper-based, 250 on computer-based, or 100 on Internet-based; or

- PTE Academic: 68

Supporting documents not submitted online should be mailed to:

George Washington University
 ATTN: Transcript Processing Center
 8300 Norman Center Dr
 Suite 400
 Bloomington, MN 55437

Alternatively, official electronic transcripts can be sent to transcripts@hsprograms.gwu.edu.

Contact for questions:

hsphora@gwu.edu
 202-994-0384 (phone)
 202-994-0870 (fax)
 Hours: 9 am to 5 pm, Monday through Friday

REQUIREMENTS

The following requirements must be fulfilled: 36 credits, including 21 credits in required core courses and 15 credits in required and elective courses in either the regulatory affairs concentration or the clinical research administration concentration.

Code	Title	Credits
Required core courses		
HSCI 6264	Epidemiology Translational Research	

COHM 6235 Leadership Development in Healthcare Systems

COHM 6245 Strategic and Operational Decision Making for Healthcare Leaders

RCR 6201 Introduction to Global Regulatory Affairs and Clinical Research

RCR 6202 Regulatory Strategy in the Development of Therapeutics

RCR 6206 International Regulatory Affairs and Clinical Research

RAFF 6275 Leadership in Regulatory Affairs

or CRA 6275 Leadership and Change in Clinical Research Administration

Concentration requirements

Students must complete all requirements for either the regulatory affairs concentration or the clinical research administration concentration, as follows:

Regulatory affairs concentration

RAFF 6203 Regulatory Strategy in the Development of Devices and Diagnostics

RAFF 6204 Clinical Research for Regulatory Affairs

RAFF 6205 Regulatory Affairs Compliance

RAFF 6207 Advertising and Promotion of Regulated Medical Products

And one course selected from the following:

CRA 6203 Partnerships with Human Subjects

CRA 6209 Quality and Risk Management

CRA 6211 Monitoring, Auditing,
and Oversight in
Clinical Research

HSCI 6263 Biostatistics
Translational Research

Clinical research administration concentration

CRA 6203 Partnerships with
Human Subjects

CRA 6204 The Clinical Research
Industry

CRA 6209 Quality and Risk
Management

CRA 6211 Monitoring, Auditing,
and Oversight in
Clinical Research

And one course selected from the following:

HCQ 6201 Building a Quality
Culture

HSCI 6263 Biostatistics
Translational Research

RAFF 6204 Clinical Research for
Regulatory Affairs

RAFF 6205 Regulatory Affairs
Compliance

RAFF 6207 Advertising and
Promotion of
Regulated Medical
Products